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QUALITY AND REGULATORY AFFAIRS

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April 6, 2000

Docket No. 00D-0053 Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
(HFA-305) Room 1061
5630 Fishers Lane
Rockville, MD 20852

Subject: Comments on Docket No. 005-0053—Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme

It is believed that Flowchart 1- Infection Risk – will not be able to be implemented until some number of years has elapsed. Question 2 requires postmarket information obtained from reprocessed devices. This information is not available in sufficient numbers and detail to make an informed judgment on increased risk of infection. Without this information, it will not be possible to make a decision regarding High Risk or moving on to Question 3.

For example, Dr. Feigal, before the oversight subcommittee on February 10, 2000, stated that a review of 300,000 MDR reports received from August 19,1996 through December 7, 1999 revealed 464 reports that could possibly be attributed to reuse. This might indicate that reprocessing is reasonably safe but the statement begs the following questions:

How many of the 300,000 MDRs were for reprocessed devices?
Do the 464 come from a few or many reprocessed devices?
Do the 464 come from devices that would be expected to have problems due to reprocessing or do they come from devices that should not be affected by reprocessing?
What is the distribution of the 464 with respect to the number of reprocessing cycles? That is, did the reports come after one or a few cycles of reprocessing or did they come after several cycles of reprocessing?
How many of the 464 were for death or serious injury?
How many were due to problems with sterilization?
How many were due to the reprocessing procedures?
How many were due to performance?

From data thus far presented by the Agency, it appears that the necessary postmarket information and its detail are not available. For each device subject to reprocessing, it is not likely that such data will be available for some time.

If the Flowchart 1 cannot be used, it is not possible to determine infection risk by this proposal. Is believed that infection risk due to reprocessing cannot be determined by a flow chart but must

be determined by proper and adequate testing of a given reprocessing procedure for each device. In broad terms, the Quality System Regulation might be considered to be sufficient for addressing this concern. The QSR, though, is merely a framework for judging that a quality system is in compliance. Detailed information on individual processes is required before determinations can be made as to their adequacy for assuring the safety and efficacy of a reprocessed device. Further, the testing must be able to determine how many reprocessing cycles can occur before the device is no longer reasonably safe and effective.

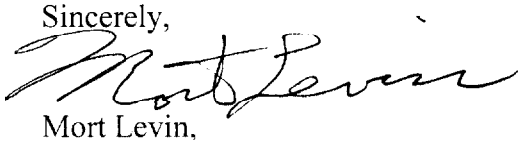
Flowchart 2 cannot be used. The first question requires postmarket information. It will not be able to be answered for quite some period of time. Question 2a cannot be answered for a long time because performance standards for devices that are proposed for reprocessing are essentially nonexistent. Development of such standards will take some years after decisions are made to begin work on these standards.

The dilemma is appreciated. Because of the pressure to reduce costs, increased reprocessing is occurring. At the same time, the safety of the patient must be paramount. Anecdotal evidence suggests that reprocessing does not pose serious problems. On the other hand, there is a lack of data to support the anecdotal statements. There is also a lack of data to support that reprocessing is reasonably safe and effective. This is particularly true when the problems of sterilizing some devices, their bioburdens, possible changes in critical material characteristics or dimensions, and the number of cycles that can be undertaken are considered.

A statement by the manufacturer that a device is for single use means that the manufacturer can only be reasonably assured of the device's safety and effectiveness for one use. Since the manufacturer cannot control the reprocessing or the reprocessing procedures of another party, the manufacturer is not in a position to determine the number of cycles of reprocessing that are possible before problems can arise. Because of the nature of devices designed for single use, it is reasonable to assume that validation testing on a statistical basis has been done by the manufacturer to provide a high degree of confidence that the device will be reasonably safe and effective for only one use.

If the above is correct, it follows that any reprocessor must demonstrate, with data from validation testing, that the reprocessing procedures provide devices that are reasonably safe and effective. This means that the reprocessor must work with a sufficient number of devices in order to provide statistically valid data. It is believed that such reprocessors fall under all of the provisions of the ACT that apply to manufacturers. Hence, any reprocessor must register and demonstrate to the Agency that the reprocessing is providing devices that are reasonably safe and effective.

Sincerely,



Mort Levin,
President

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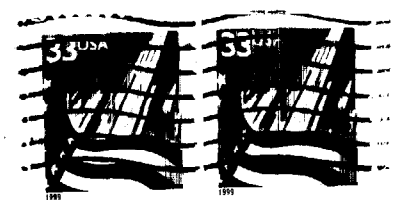

Returned For Better Address

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